

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED ~~(CON)~~ REVIEW STANDARDS
FOR HEART/LUNG AND LIVER TRANSPLANTATION SERVICES

(By authority conferred on the ~~Certificate of Need~~CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and Sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being Sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and ~~Certificates of Need~~CONS issued under Part 222 of the Code which involve heart/lung or liver transplantation services.

(2) Heart/lung or liver transplantation is a covered clinical service for purposes of Part 222 of the Code.

(3) For purposes of Part 222 a separate ~~Certificate of Need~~CON is required for heart/lung or liver transplantation services. A ~~Certificate of Need~~CON issued for a heart/lung transplantation service includes a service that performs heart, heart/lung, or lung transplant procedures and a separate ~~Certificate of Need~~CON is not required to begin performing any of these procedures if one or more are not performed initially.

(4) The Department shall use Sections 3, 4, 5, and 11, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(5) The Department shall use Sections 7, 8, 9, and 10, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Certificate of Need Commission" or "CON Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(b) "Comparative group" means the applications ~~which that~~ have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the ~~Certificate of Need~~CON rules.

(c) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 ~~et seq.~~ of the Michigan Compiled Laws.

(d) "Department" means the ~~state agency known as the~~ Michigan Department of Community Health (MDCH).

(e) "Health service area" or "HSA" means the geographic area set forth in Section 12.

(f) "Implementation plan" means a plan that documents how a proposed transplantation service will be initiated within the time period specified in these standards or the ~~Certificate of Need~~CON rules. At a minimum, the implementation plan shall identify: (i) each component or activity necessary to begin performing the proposed transplantation service, including but not limited to, the development of physical plant requirements such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff; (ii) the time table for completing each component or activity specified in subsection (i); and (iii) if the applicant previously has been approved for a transplantation service for which either the ~~Certificate of Need~~CON expired or the service did not perform a transplant procedure during any consecutive 12-month period,

53 what changes have or will be made to ensure that the proposed service can be initiated and provided on a
54 regular basis.

55 (g) "Initiate" or "implement" for purposes of these standards, means the performance of the first
56 transplant procedure. The term of an approved ~~Certificate of Need~~ **CON** shall be 18 months or the
57 extended period established by Rule 325.9403(2), if authorized by the Department.

58 (h) "Licensed site" means either (i) in the case of a single site hospital, the location of the facility
59 authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital
60 with multiple sites, the location of each separate and distinct inpatient unit of the health facility as
61 authorized by license and listed on that licensee's certificate of licensure.

62 (i) "Medicaid" means ~~the program for medical assistance administered by the Department of~~
63 ~~Community Health under~~ **TITLE XIX OF the Social Welfare SECURITY Act, CHAPTER 531, 49 STAT.**
64 **620, 1396R-6 AND 1396R-8 TO 1396V, Act No. 280 of the Public Acts of 1939, being Sections 400.1 to**
65 **400.119b of the Michigan Compiled Laws.**

66 (j) "OPO" or "Organ Procurement Organization" means an organ procurement organization as
67 defined by Title 42, Part 485.302.

68 (k) "OPTN" or "Organ Procurement and Transplantation Network" means the organization contracted
69 by the federal Department of Health and Human Services to operate the organ procurement and
70 transplantation network.

71 (l) "Pediatric" means, for purposes of these standards, any patient less than 15 years of age or any
72 patient with congenital anomalies related to the proposed transplantation service.

73 (m) "Planning area" means the state of Michigan.

74 (n) "Qualifying project" means each application in a comparative group which has been reviewed
75 individually and has been determined by the Department to have satisfied all of the requirements of
76 Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other
77 applicable requirements for approval in the Code and these standards.

78 (o) "Survival rate" means, for purposes of these standards, the rate calculated using the Kaplan-
79 Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is
80 performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii)
81 for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed
82 as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as
83 surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are
84 calculated and its experience is reported), survival is considered to be the date of the last ascertained
85 survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead but
86 whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be
87 considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient
88 transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if
89 he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days
90 before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be
91 considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been
92 ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient
93 in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an
94 applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as
95 alive at the date of the last ascertained survival.

96 (p) "Transplant and Health Policy Center" means the statewide organization which studies issues
97 regarding organ transplantation and other emerging health care technologies and operates the organ
98 transplant registry.

99 (q) "Transplant support program" means, for purposes of these standards, a program where a
100 hospital providing a transplantation service has a written agreement with one or more hospitals to
101 coordinate the care of transplant patients residing outside the HSA in which the hospital providing the
102 transplantation service is located in order that patients may receive transplant-related services, to the
103 maximum extent practical, at the hospital with which the agreement is written. The program shall be
104 active on the date an application is submitted to the Department having accepted potential transplant

recipient(s) into the program.

(2) The definitions of Part 222 shall apply to these standards.

Section 3. Requirements for approval -- all applicants

Sec. 3. (1) An applicant proposing to perform either a heart, heart/lung, or lung or liver transplantation service shall demonstrate that it offers all of the following services or programs:

- (a) operating rooms;
- (b) anesthesiology;
- (c) microbiology and virology laboratory;
- (d) continuous availability, either on-site or on-call, of:
 - (i) diagnostic imaging services including CT scanning; magnetic resonance imaging; and nuclear medicine; and (ii) a broad range of sub-specialty consultants, adult and pediatric, as appropriate, in both medical and surgical specialties including but not limited to: pulmonary medicine with respiratory therapy support; cardiology; gastroenterology; pediatrics, as appropriate; nephrology; and immunology.
- (e) dialysis;
- (f) infectious disease;
- (g) inpatient-outpatient social work;
- (h) inpatient-outpatient psychiatry/psychology;
- (i) clinical research;
- (j) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization, either on-site or through written agreement;
- (k) other support services, as necessary, such as physical therapy and rehabilitation medicine;
- (l) continuous availability of anatomic and clinical pathology and laboratory services including clinical chemistry, immuno-suppressive drug monitoring and tissue typing;
- (m) continuous availability of red cells, platelets, and other blood components;
- (n) an established organ donation protocol, with brain death protocol, consistent with applicable Michigan law; and
- (o) a written agreement with Michigan's federally designated organ procurement organization (OPO) to promote organ donation at the applicant hospital(s).

(2) An applicant must provide, at the time the ~~Certificate of Need~~ CON application is submitted, an implementation plan for the proposed transplantation service.

(3) An application which proposes a joint sharing arrangement for a transplantation service which involves more than one licensed site shall demonstrate all of the following:

- (a) all licensed sites in the joint sharing arrangement are part of a single legal entity authorized to do business in Michigan;
- (b) all licensed sites in the joint sharing arrangement are geographically close enough so as to facilitate cost-effective sharing of resources;
- (c) an applicant has designated a single licensed site where the transplant surgical procedure(s) will be performed, except that where an applicant proposes a joint sharing arrangement which involves both adult and pediatric transplant procedures, the applicant may designate a single licensed site where all adult transplant procedures will be performed and a single licensed site where all pediatric transplant procedures will be performed, if:
 - (i) both licensed sites are part of the joint sharing arrangement;
 - (ii) the same transplant coordinator will serve patients at both licensed sites;
 - (iii) laboratory procedures related to the proposed transplantation service will be performed at a single common laboratory operated by the applicant;
 - (iv) all physicians performing the proposed transplantation procedures at either licensed site are part

of a common organizational entity (i.e., partnership, professional corporation, or medical school faculty); and

(v) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation procedures under the same OPTN certification.

(4) AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. IF THE REQUIRED DOCUMENTATION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY THE DEPARTMENT.

Section 4. Additional requirements for applicants seeking approval to provide heart or heart/lung or lung transplantation services

Sec. 4. (1) Approval of an application proposing to provide heart or heart/lung or lung transplantation services shall not result in more than three (3) heart or heart/lung or lung transplantation services in the planning area. In evaluating compliance with this subsection, an application submitted or a certificate approved pursuant to Section 4(5) of these standards shall be considered as a single service.

(2) Except for an application pursuant to Section 4(5) of these standards, an applicant for a heart or heart/lung or lung transplantation service shall project a minimum of 12 heart or heart/lung or lung transplantation procedures annually in the second 12-months of operation following the date on which the first heart or heart/lung or lung transplant procedure is performed and annually thereafter.

(3) An applicant proposing to provide heart or heart/lung or lung transplantation services shall demonstrate that it either operates an existing renal transplant service or has a written agreement with a renal transplant service in the same hospital subarea that ensures that the professional expertise of the renal transplant service is readily available to the proposed transplantation service.

(4) An applicant proposing to provide a heart or heart/lung or lung transplantation service shall demonstrate that it offers all of the following services or programs:

(a) a cardiovascular medical/surgical program that includes at least the following: (i) an open heart surgery service that performs at least 300 adult and/or 100 pediatric procedures annually, as applicable; and (ii) a cardiac catheterization service that performs at least 500 adult and/or 250 pediatric cardiac catheterizations and coronary arteriograms annually, as applicable, and has the capability to perform these procedures on an emergency basis.

(b) continuous availability, either on-site or on-call, of angiography services;

(c) an intensive care unit with 24-hour per day on-site physician coverage;

(d) continuously available coagulation laboratory services; and

(e) a blood bank capable of providing 20 units of blood, platelets, and fresh blood products on demand.

(5) An application which proposes a joint sharing arrangement for a heart or heart/lung or lung transplantation service which involves more than one licensed site, where the licensed sites in the joint sharing arrangement are not part of a single legal entity authorized to do business in Michigan, shall not be required to meet Section 4(1) of these standards, if an applicant can demonstrate all of the following:

(i) each licensed site in the joint sharing arrangement is party to a written joint venture agreement and each licensed site has jointly filed as the applicant for the ~~Certificate of Need~~CON;

(ii) all licensed sites in the joint sharing arrangement are geographically close enough so as to facilitate cost-effective sharing of resources;

(iii) the application contains a formal plan for the sharing of services, staff and administrative

functions related to the transplantation service, including but not limited to: patient review, patient selection, donor organ retrieval and patient care management;

(iv) an applicant has designated a single licensed site where all of the adult transplantation procedures will be performed and a single licensed site where all of the pediatric transplantation procedures will be performed, provided that both licensed sites are part of the joint sharing arrangement;

(v) the licensed site at which the pediatric transplantation service will be provided shall have admitted or discharged at least 7,000 pediatric patients during the most recent 12-month period for which verifiable data are available to the Department;

(vi) the licensed site that is designated as the site at which adult procedures will be performed is authorized under former Part 221 or Part 222, at the time the application is submitted to the Department, to perform adult heart or heart/lung or lung transplantation services;

(vii) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation procedures under the same OPTN certification; and

(viii) the applicant projects a minimum of 12 adult and 10 pediatric heart or heart/lung or lung transplantation procedures in the second 12-months of operation following the date on which the first heart or heart/lung or lung transplant procedure is performed, and annually thereafter.

Section 5. Additional requirements for applicants seeking approval to provide liver transplantation services

Sec. 5. (1) Approval of an application proposing to provide liver transplantation services shall not result in more than three (3) liver transplantation services in the planning area.

(2) An applicant for a liver transplantation service shall project a minimum of 12 liver transplantation procedures annually in the second 12-months of operation following the date on which the first liver transplant procedure is performed, and annually thereafter.

(3) An applicant proposing to provide liver transplantation services shall demonstrate that it either operates an existing renal transplant service or has a written agreement with a renal transplant service in the same hospital subarea that ensures that the professional expertise of the renal transplant service is readily available to the proposed transplantation service.

(4) An applicant proposing to provide a liver transplantation service shall demonstrate that it offers all of the following services or programs:

- (a) continuous availability, either on-site or on-call, of angiography services;
- (b) an intensive care unit with 24-hour per day on-site physician coverage;
- (c) endoscopic retrograde cholangiopancreatography (ERCP) availability;
- (d) percutaneous cholangiogram availability;
- (e) percutaneous liver biopsy capability;
- (f) a rapid blood infusion system;
- (g) hemoperfusion; and
- (h) a rapid red blood cell (RBC) blood saver system.

Section 6. Additional requirements for applications included in comparative reviews

Sec. 6. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or these standards shall be grouped and reviewed with other applications in accordance with the ~~Certificate of Need~~ CON rules applicable to comparative reviews.

(2)(a) A qualifying project will be awarded points based on the percent of compliance with the Uniform Anatomical Gift Law, Act No. 186 of the Public Acts of 1986, being Section 333.10101 et seq. of the

Michigan Compiled Laws. The number of points awarded shall be calculated by dividing the number of deaths reported to the OPO by the total number of eligible deaths reported to the Department and multiplying the product by 4. The maximum number of points that can be awarded under this subsection is 4. An applicant shall provide, in the application at the time it is submitted to the Department, documentation of the total number of eligible deaths at the licensed site at which the proposed transplantation service will be provided, for the most recent year for which the Department has verifiable data.

(b) A qualifying project will have points awarded based on the number of transplantation services of the type proposed, both operating and ~~Certificate of Need~~ CON approved, but not yet operational, in the health service area in which the proposed program will be located, on the date the application is submitted to the Department, as shown in the following schedule:

Number of Transplant Programs in HSA	Points Awarded
Two or more programs	0
One program	2
No programs	4

(c) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed hospital site at which the proposed heart/lung or liver transplantation service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume, rounded to the nearest whole number, for each licensed hospital site at which a heart/lung or liver transplantation service is proposed to be provided. Determine the licensed hospital site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed hospital site by 4.0. The result is the indigent volume factor.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the first decimal place, is the number of points that will awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Michigan Department of Community Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Hospital Program Manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(d) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the heart/lung or liver transplant procedures will be performed and were referred for and received a heart/lung or liver transplant at an existing heart/lung or liver transplantation service, and submits documentation from the existing heart/lung or liver transplantation service(s) of these referrals.

(3) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying

313 projects are determined to have an identical number of points, the Department shall approve those
314 qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the
315 Code, being Section 333.22225(1) of the Michigan Compiled Laws, in the order in which the applications
316 were received by the Department, based on the date and time stamp placed on the application for
317 ~~Certificate of NeedCON~~ form (form T-150-G-1.01 or any subsequent replacement form) by the Division of
318 Health Facility Development (or the administrative unit of the Department responsible for administering the
319 ~~Certificate of NeedCON~~ program) when an application is submitted.

320
321 (4) No points will be awarded to an applicant under specific subsections of Section 6 if information
322 presented in Section 6 is inconsistent with related information provided in other portions of the ~~Certificate~~
323 ~~of NeedCON~~ application.

324 325 **Section 7. Project delivery requirements -- terms of approval for all applicants**

326
327 Sec. 7. (1) An applicant shall agree that, if approved, the services shall be delivered in compliance
328 with the following terms of ~~Certificate of NeedCON~~ approval:

329 (a) Compliance with these standards. An applicant shall immediately report to the Department any
330 changes in key staff or other aspects of the transplantation service that may affect its ability to comply with
331 these standards.

332 (b) Compliance with applicable safety and operating standards.

333 (c) Compliance with the following quality assurance standards, as applicable:

334 (i) The applicant shall perform the applicable required volumes within the time periods specified in
335 these standards, and annually thereafter.

336 (ii) The applicant shall comply with applicable OPTN and Medicare requirements.

337 (iii) The transplantation service shall have a transplant team leader and coordinator.

338 (iv) The applicant shall have patient management plans and protocols that include the following: (A)
339 therapeutic and evaluative procedures for the acute and long-term management of a patient; (B) patient
340 management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the
341 service; and (C) long-term management and evaluation, including education of the patient, liaison with the
342 patient' s attending physician, and the maintenance of active patient records for at least 5 years.

343 (v) The applicant shall implement a program of education and training for nurses, technicians, service
344 personnel, and other hospital staff.

345 (vi) An applicant shall actively participate in the education of the general public and the medical
346 community with regard to transplantation, and will make organ donation literature available in public areas
347 of the institution.

348 (vii) The applicant shall establish and maintain an active, formal multi-disciplinary research program
349 related to the proposed transplantation service.

350 (viii) The applicant' s education and research program related to transplantation shall be subject to
351 external peer review.

352 (ix) The applicant shall maintain an organized institutional transplant registry for recording ongoing
353 information on its patients being evaluated for transplant and on its transplant recipients and shall
354 participate in the statewide transplantation registry operated by the Transplant and Health Policy Center
355 and other national and international registries applicable to the transplantation service.

356 (x) The applicant shall participate in a data collection network established and administered by the
357 Department ~~OR ITS DESIGNEE~~. The data may include, but is not limited to, annual budget and cost
358 information, operating schedules, through-put schedules, demographic and diagnostic information, patient
359 survival rates at both 12 and 24 months following the transplant procedure, primary and secondary
360 diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the
361 volume of care provided to patients from all payor sources, and other data requested by the Department
362 and approved by the ~~Certificate of NeedCON~~ Commission. The applicant shall provide the required data
363 on an individual basis for each designated licensed site; in a format established by the Department; and in
364 a mutually agreed upon media. The Department may elect to verify the data through on-site review of

appropriate records.

(xi) The applicant, to assure that the transplantation service(s) will be utilized by all segments of the Michigan population, shall:

(A) not deny the services to any individual based on ability to pay or source of payment;

(B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; and

(C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(xii) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department ~~CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES~~ ~~within 10 days after the first transplant procedure is performed.~~

(xiii) The transplantation service must operate, or have a written agreement with, a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

~~(XIV) AN APPLICANT SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.~~

(d) Compliance with the Uniform Anatomical Gift Law, Act No. 186 of the Public Acts of 1986, being Section 333.10101 et seq. of the Michigan Compiled Laws.

(2) The agreements and assurances required by this section, and Sections 8, 9, and 10, as applicable, shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 8. Additional terms of approval -- applicants proposing heart, heart/lung, lung or liver transplantation services

Sec. 8. (1) An applicant shall agree to establish and maintain all of the following:

(a) a written agreement with the federally approved organ procurement organization whose designated service area includes the location of the proposed transplantation service;

(b) organ preservation capability;

(c) an organized 24-hour transport system for transportation of organs, donors, and blood serum;

(d) an organized 24-hour communication service capable of serving the transplant team and others, as appropriate;

(e) a cyclosporine assay laboratory with results available on the same day;

(f) an immunologic monitoring laboratory;

(g) a specialized inpatient transplantation unit;

(h) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used in conjunction with the transplantation service, trained in the hemodynamic support of the transplant patient and managing immuno-suppressed patients.

(i) a medical staff and governing board policy that provides for the selection of candidates for organ transplantation procedures in accordance with the patient selection criteria approved by the Department;

(j) an ethics committee or human use committee to review and approve the institution's protocols related to organ transplantation, including protocols involving the selection of donors and recipients; and

(k) a multi-disciplinary transplant recipient evaluation committee.

(2) An applicant shall agree that the transplantation service shall be staffed with qualified adult and pediatric, as applicable, transplant surgeon(s) and transplant physician(s). For purposes of evaluating this subsection, the Department shall consider it prima facie evidence as to the training of the surgeon(s) and physician(s) if they meet the requirements for certification by Medicare or the OPTN. However, the

applicant may submit and the Department may accept other evidence that the surgeon(s) and physician(s) are qualified.

Section 9. Additional terms of approval -- applicants proposing heart or heart/lung or lung transplantation services

Sec. 9. (1) An applicant shall agree that the heart or heart/lung or lung transplantation service will be staffed and provided by at least the following:

- (a) cardiologists or surgeons trained in endocardial biopsy;
- (b) cardiologists and surgeons trained in immunosuppression techniques;
- (c) both adult and pediatric, as appropriate, cardiologists and surgeons;
- (d) surgeons with demonstrated capability of successfully performing orthotopic cardiac transplants in animals in a setting simulating the human situation;
- (e) two cardiac transplant surgical teams with a total of at least three trained cardiac surgeons, with one surgical team continuously available for organ retrieval thereby enabling a second team to simultaneously begin performing a recipient operation;
- (f) a pathologist capable of diagnosing rejection on endocardial biopsies; and
- (g) an anesthesiologist trained in open heart surgery.

(2) An applicant must demonstrate heart transplant patient survival rates at one year and two years after transplantation of 73% and 65%, respectively. For lung and heart/lung, an applicant must demonstrate patient survival rates at one and two years after transplantation of no less than the national average survival rate for the specific transplant type for the most recent year for which data is published by the OPTN.

Section 10. Additional terms of approval -- applicants proposing liver transplantation services

Sec. 10. (1) An applicant shall agree that the liver transplantation service will be staffed and provided by at least the following:

- (a) surgeons with demonstrated capability of successfully performing hepatic transplants in animals in a setting simulating the human situation;
- (b) surgeons with demonstrated proficiency in major hepatic surgery such as hepatic lobectomy, repair of biliary strictures, and Porto systemic shunts;
- (c) adult and pediatric, as appropriate, gastroenterologists and hematologists on the active medical staff;
- (d) a pathologist capable of diagnosing hepatic rejection;
- (e) anesthesiologist(s) trained in liver transplantation;
- (f) two liver transplant surgical teams, with one surgical team continuously available for organ retrieval thereby enabling a second team to simultaneously begin performing recipient hepatectomy in preparation for liver implantation; and
- (g) cardiopulmonary bypass equipment and a cardiopulmonary bypass team immediately available for a liver transplant recipient operation, a requirement which may be satisfied by a written agreement which ensures that a cardiopulmonary bypass team will always be on-site throughout the entire liver transplant recipient operation; and, a veno-venous bypass system which does not require heparin.

(2) The applicant shall establish and maintain all of the following:

- (a) nuclear HID biliary scan availability;
- (b) a continuously available coagulation laboratory; and
- (c) a blood bank system capable of providing 200 units of blood or packed cells and 100 units of plasma on demand.

(3) An applicant must demonstrate patient survival rates at one year and two years after

transplantation of no less than the national average survival rate for the most recent year for which data is published by the OPTN.

Section 11. Documentation of projections

Sec. 11. An applicant required to project volumes of service under Sections 4 or 5 shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 12. Health Service Areas

Sec. 12. Counties assigned to each of the health service areas are as follows:

<u>HSA</u>		<u>COUNTIES</u>	
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton Eaton	Hillsdale Ingham	Jackson Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon Schoolcraft

521 **Section 13. Effect on prior ~~Certificate of Need~~CON Review Standards; comparative reviews** |

522
523 Sec. 13. (1) These ~~Certificate of Need~~CON review standards supersede and replace the ~~Certificate of~~
524 ~~Need~~CON Review Standards for Extrarenal Transplantation Services approved by the ~~Certificate of~~
525 ~~Need~~CON Commission ~~ON JUNE 4, 1997~~ and effective on ~~December 18, 1993~~JULY 26, 1997.

526
527 (2) Projects reviewed under these standards shall be subject to comparative review.